

B1



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

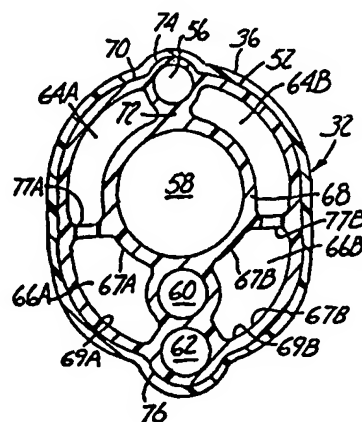
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61N 5/02		A1	(11) International Publication Number: WO 96/39227
			(43) International Publication Date: 12 December 1996 (12.12.96)
(21) International Application Number: PCT/US96/07878 (22) International Filing Date: 29 May 1996 (29.05.96) (30) Priority Data: 08/469,201 6 June 1995 (06.06.95) US (71) Applicant: UROLOGIX, INC. [US/US]; 14405 21st Avenue North, Minneapolis, MN 55427 (US). (72) Inventors: THOME, Scott, P.; 535 Aberdeen Drive, Waite Park, MN 56387 (US). FLACHMAN, Jonathan, L.; 3300 Kyle Avenue North, Minneapolis, MN 55422 (US). (74) Agent: GRUNZWEIG, Paul, S.; Kinney & Lange, P.A., Suite 1500, 625 Fourth Avenue South, Minneapolis, MN 55415-1659 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>	

(54) Title: **DEVICE FOR TRANSURETHRAL THERMAL THERAPY**

(57) Abstract

An intraurethral catheter shaft (32) comprises a plurality of lumens extending between a first end and a second end of the shaft (32). An antenna lumen (58) has a generally circular cross-sectional surface area and is positioned nearer a first outer surface (70) than a second outer surface (76) of the catheter shaft (32). A first and second pair of cooling lumens (64A, 64B and 66A, 66B) substantially surround the antenna lumen (58) and have a generally arc shaped cross-sectional surface area. The cooling lumens are configured to be circumjacent to the antenna lumen (58) about a substantial majority of the antenna lumen (58). A urinary drainage lumen (60) is positioned between the second pair of cooling lumens (66A, 66B) adjacent the antenna lumen (58) and has a generally circular cross-sectional surface area. The lumens of the catheter shaft (32) are defined by a unitary wall (68) having a substantially uniform thickness throughout the catheter (28).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

-1-

DEVICE FOR TRANSURETHRAL THERMAL THERAPY**BACKGROUND OF THE INVENTION**

The present invention relates to the field of microwave thermal therapy of tissue. In particular, the present invention relates to a catheter for transurethral microwave thermal therapy of benign prostatic hyperplasia (BPH).

The prostate gland is a complex, chestnut-shaped organ which encircles the urethra immediately below the bladder. Nearly one third of the prostate tissue anterior to the urethra consists of fibromuscular tissue that is anatomically and functionally related to the urethra and bladder. The remaining two thirds of the prostate is generally posterior to the urethra and is comprised of glandular tissue.

This relatively small organ, which is the most frequently diseased of all internal organs, is the site of a common affliction among older men: BPH (benign prostatic hyperplasia). BPH is a nonmalignant, bilateral nodular expansion of prostate tissue in the transition zone, a periurethral region of the prostate between the fibromuscular tissue and the glandular tissue. The degree of nodular expansion within the transition zone tends to be greatest anterior and lateral to the urethra, relative to the posterior-most region of the urethra. Left untreated, BPH causes obstruction of the urethra which usually results in increased urinary frequency, urgency, incontinence, nocturia and slow or interrupted urinary stream. BPH may also result in more severe complications, such as urinary tract infection, acute urinary retention, hydronephrosis and uraemia.

Traditionally, the most frequent treatment for BPH has been surgery (transurethral resection). Surgery, however, is often not an available method of treatment for a variety of reasons. First, due to the advanced age of many patients with BPH, other health problems, such as cardiovascular disease, can warrant against surgical intervention. Second, potential complications associated with transurethral surgery, such as hemorrhage, anesthetic

-2-

complications, urinary infection, dysuria, incontinence and retrograde ejaculation, can adversely affect a patient's willingness to undergo such a procedure.

A fairly recent alternative treatment method for BPH involves
5 microwave thermal therapy, in which microwave energy is employed to elevate the temperature of tissue surrounding the prostatic urethra above about 45°C, thereby thermally damaging the tumorous tissue. Delivery of microwave energy to tumorous prostatic tissue is generally accomplished by a microwave antenna-containing applicator, which is positioned within a body cavity adjacent the
10 prostate gland. The microwave antenna, when energized, heats adjacent tissue due to molecular excitation and generates a cylindrically symmetrical radiation pattern which encompasses and necroses the tumorous prostatic tissue. The necrosed intraprostatic tissue is subsequently reabsorbed by the body, thereby relieving an individual from the symptoms of BPH.

15 One method of microwave thermal therapy described in the art includes intrarectal insertion of a microwave antenna-containing applicator. Heat generated by the antenna's electromagnetic field is monitored by a sensor which is positioned near the prostate gland by a urethral catheter. Because of the distance between the rectum and the tumorous prostatic tissue of the
20 transition zone, however, healthy intervening tissue within the cylindrically symmetrical radiation pattern is also damaged in the course of intrarectal treatment. Intrarectal microwave thermal therapy applicators are described in the following references: Eshel et al. U.S. Patent No. 4,813,429; and A. Yerushalmi et al. Localized Deep Microwave Hyperthermia in the Treatment of
25 Poor Operative Risk Patients with Benign Prostatic Hyperplasia, 133 JOURNAL OF UROLOGY 873 (1985).

A safer and more effective treatment of BPH is transurethral microwave thermal therapy. This method of treatment minimizes the distance between a microwave antenna-containing applicator and the transition zone of

-3-

the prostate by positioning a Foley-type catheter-bearing applicator adjacent to the prostate gland within the urethra. Due to the close proximity of the microwave antenna to the prostate, a lesser volume of tissue is exposed to the cylindrically symmetrical radiation pattern generated by the microwave antenna, thereby minimizing the amount of healthy tissue necrosed. Intraurethral applicators of the type described can be found in Turner et al. U.S. Patent 4,967,765 and Hascoet et al. European Patent Application 89403199.6.

Recent improvements in transurethral thermal therapy catheter design have resulted in even more effective application of microwave radiation applied to prostatic tissue. For instance, recent transurethral catheters such as that described in Rudie U.S. Patent No. 5,413,588, issued May 9, 1995, include shafts having a multiplicity of lumens arranged about a lumen carrying a microwave antenna. The antenna lumen is oriented nearer a first side of the catheter shaft than a second side of the catheter shaft to position the microwave radiation closer to the first side of the catheter. Cooling lumens are arranged about the microwave antenna lumen to absorb a portion of the microwave radiation so that a greater amount of microwave radiation is absorbed on a second side of the catheter shaft than the first side. This arrangement creates an asymmetrical microwave radiation pattern to permit focusing a greater amount of microwave radiation toward a selected tissue, such as prostatic tissue anterior and lateral to the urethra. This transurethral catheter design also includes a lumen to facilitate urinary drainage from the bladder through the urethra during a treatment session.

SUMMARY OF THE INVENTION

The present invention is based upon the recognition that although the catheter disclosed in Rudie et al. U.S. Patent No. 5,413,588 offers a substantial improvement over previous designs, transurethral catheter designs can still be improved. In particular, improvements can still be made in maintaining consistent urine drainage, increasing antenna tuning consistency,

-4-

maximizing selective energy absorption of the area immediately surrounding the microwave antenna lumen, and simplifying manufacture of the catheter shaft while improving its structural integrity. In addition, transurethral catheter designs can be improved to facilitate insertion of the catheter within the urethra while also simplifying manufacture of the catheter.

An intraurethral catheter of the present invention comprises a shaft including an antenna lumen having a generally circular cross-sectional area for receiving a microwave antenna. The antenna lumen is positioned nearer a first side of the catheter shaft than a second side of the catheter shaft. The microwave antenna, when energized, produces a cylindrically symmetrical radiation pattern about the antenna.

A first and second pair of cooling lumens substantially surround the antenna lumen and have a generally arc shaped cross-sectional area configured to be circumjacent to the antenna lumen about a substantial majority of the antenna lumen. The second pair of cooling lumens have a cross-sectional area greater than the cross-sectional area of the first pair of cooling lumens. A urinary drainage lumen is positioned between the second pair of cooling lumens adjacent the antenna lumen and has a generally circular cross-sectional surface area.

The generally arc shaped cross-sectional surface area of the cooling lumens is configured to maximize exposure of the surface area of the cooling lumens to the antenna lumen. The generally arc shape of the cooling lumens places an inner wall of the cooling lumens immediately circumjacent a substantial majority of the antenna lumen. This configuration maximizes efficiency of the cooling lumens in counteracting heat generated by the microwave antenna in a region immediately surrounding the antenna and the catheter shaft.

The first pair of cooling lumens are positioned adjacent the first side of the catheter shaft while the larger second pair of cooling lumens are

-5-

positioned adjacent the second side. The larger, second pair of cooling lumens (when filled with fluid) absorb a greater amount of microwave energy than the first pair of cooling lumens to produce a preferential asymmetrical radiation pattern in the prostatic tissue being treated. In combination with the eccentric position of the antenna lumen, the cooling lumen configuration about the antenna lumen permits heating of prostatic tissue adjacent a first side of the catheter above 45°C to necrose tumorous tissue while maintaining tissue adjacent the second side below 45°C to preserve healthy tissue.

The generally circular cross-sectional surface area of the urinary drainage lumen is configured to minimize exposure of the surface area of the urinary drainage lumen relative to an antenna lumen also having a generally circular cross section. The generally circular cross-sectional shape of the urine drainage lumen places only a point of the circular lumen immediately adjacent the generally circular cross-section of the antenna lumen. The generally circular shape of the urinary drainage lumen and its placement relative to the antenna lumen reduces the effect that variability in urine flow has on the radiation pattern generated by the microwave antenna.

In addition, providing a urinary drainage lumen with a generally circular cross-sectional area greatly improves the likelihood of the lumen remaining open when a portion of the catheter shaft is positioned into a curved or bent position within the urethra. The generally circular cross section provides a shape that can remain open even if the catheter is bent in any one of several different directions.

The lumens of the catheter shaft are preferably defined by a unitary wall having a substantially uniform thickness throughout the catheter. However, a catheter of the present invention can further include a portion of the wall of the catheter having a thickness of about two times the substantially uniform wall thickness and defining a common wall of the antenna lumen and the temperature sensing lumen. In addition, a second portion of the wall of the

-6-

catheter can have a wall thickness of about one-half the substantially uniform thickness and define an outer wall of the temperature sensing lumen and the first outer surface of the catheter. This configuration maximizes insulation between a thermal sensing device positioned within the temperature sensing lumen and the microwave energy and heat generated by a microwave antenna positioned within the antenna lumen of the catheter shaft. This increases the accuracy of temperature measurements of the tissue surrounding the transurethral catheter.

A temperature sensing lumen of the transurethral catheter of the present invention can further include an elongate insert positioned alongside a thermal sensing device within the temperature sensing lumen between the thermal sensing device and the antenna lumen. This insert further insulates the thermal sensing device from the heat generated by the microwave antenna field and places the thermal sensing device closer to the prostatic tissue to further increase the accuracy of the thermal sensing device in measuring the temperature of the surrounding prostatic tissue. The insert also moves the thermal sensing device further away from the cooling fluid intake lumens thereby reducing the cooling effect of cooling fluids on temperature measurements taken by the thermal sensing device.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a vertical sectional view of a male pelvic region showing the urinary organs affected by benign prostatic hyperplasia.

Fig. 2 is a plan view of the urethral catheter of the present invention.

Fig. 3 is a cross-sectional view of the urethral catheter of Fig. 2 taken along line 3-3.

Fig. 4 is a cross-sectional view of the urethral catheter of Fig. 2 taken along line 4-4.

Fig. 5 is a perspective view of a proximal portion of the urethral catheter with the proximal end portion taken in section from line 5-5 of Fig. 2.

-7-

Fig. 6 is a perspective view of a combined tip and balloon of the urethral catheter of the present invention.

Fig. 7 is an enlarged sectional view of the proximal end of the urethral catheter of the present invention.

5 Fig. 8 is a partial sectional view of the temperature sensing lumen and an elongate insert of the urethral catheter of the present invention.

Fig. 9 is a cross-sectional view of the urethral catheter of Fig. 8 taken along line 9-9.

10 Fig. 10 is a cross-sectional view of an alternative embodiment of a tubular elongate insert of the present invention.

Fig. 11 is an enlarged view of the male pelvic region of Fig. 1 showing the urethral catheter of the present invention positioned within the prostate region.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 Fig. 1 is a vertical sectional view of a male pelvic region showing the effect benign prostatic hyperplasia (BPH) has on the urinary organs. Urethra 10 is a duct leading from bladder 12, through prostate 14 and out orifice 16 of penis end 18. Benign tumorous tissue growth within prostate 14 around urethra 10 causes constriction 20 of urethra 10, which interrupts the flow
20 of urine from bladder 12 to orifice 16. The tumorous tissue of prostate 14 which encroaches urethra 10 and causes constriction 20 can be effectively removed by heating and necrosing the encroaching tumorous tissue. Ideally, with the present invention, only periurethral tumorous tissue of prostate 14 anterior and lateral to urethra 10 is heated and necrosed to avoid unnecessary
25 and undesirous damage to urethra 10 and to adjacent healthy tissues, such as ejaculatory duct 24 and rectum 26. A selective heating of benign tumorous tissue of prostate 14 (transurethral thermal therapy) is made possible by microwave antenna-containing catheter 28 of the present invention, which is shown in Fig. 2.

-8-

As shown in Fig. 2, catheter 28 generally includes multi-port manifold 30, multi-lumen shaft 32, and tip 34 which includes balloon portion 36, tip portion 38, and side port 39. Manifold 30 includes inflation port 40, urine drainage port 42, microwave antenna port 44, cooling fluid intake port 46, and cooling fluid exhaust port 48. Ports 40-48 of manifold 30 communicate with corresponding lumens within shaft 32. Manifold 30 is preferably made of medical-grade silicone sold by Dow Corning under the trademark Silastic[®] Q-7-4850.

Catheter 28 can be employed in a thermal therapy catheter system further including a cooling system, a microwave generating source, and a urethral thermometry unit. These additional elements of a thermal therapy catheter system are disclosed in Rudie et al. U.S. Patent No. 5,413,588, which is hereby incorporated by reference. In particular, manifold 30 of catheter 28 of the present invention cooperates with a transurethral thermal catheter system in the same manner that manifold 30 disclosed in the Rudie patent cooperates with the multi-lumen catheter, cooling system, microwave generating source, and transurethral thermometry unit disclosed in that patent. For instance, inflation port 40 of manifold 30 of the present invention is adapted for receiving an inflation fluid for inflating balloon 36. Urinary drainage port 42 of manifold 30 is adapted to facilitate urine from catheter shaft 32, and antenna port 44 is adapted to receive a microwave antenna for insertion and positioning within the multi-lumen catheter shaft 32. Cooling fluid intake port 46 and cooling fluid exhaust port 48 are cooperable with a cooling system for providing selective flow of cooling fluids within multi-lumen catheter shaft 32.

Shaft 32 is connected to manifold 30 at shaft distal end 50. Shaft 32 is long enough to permit insertion of balloon 36 through urethra 10 and into bladder 12. Shaft 32 is a multi-lumen urethral catheter shaft which is extruded from a flexible, medical-grade silicone sold by Dow Corning under the

-9-

trademark Silastic[®] Q-7-4850. The silicone material preferably has a durometer hardness of 80 Shore A.

As shown in Fig. 3, multi-lumen shaft 32 includes temperature sensing lumen 56, microwave antenna lumen 58, urine drainage lumen 60, balloon inflation lumen 62, cooling fluid intake lumens 64A and 64B, and cooling exhaust lumens 66A and 66B. Lumens 56-66B generally extend from distal shaft end 50 to proximal shaft end 54. Lumens 56-66B are defined by unitary wall 68 which has a substantially uniform thickness throughout a cross section of catheter shaft 32. Catheter wall 68 preferably has a thickness of 0.009 inches. A center of each of lumens 56-62 is aligned along a longitudinal axis of an elliptical cross section of catheter shaft 32. Protective sheath 71 covers outer surface 52 of catheter shaft 32 and is preferably made of Teflon[®] to facilitate its advancement within urethra 10.

Temperature sensing lumen 56 is positioned near first side 70 of shaft 32. Temperature sensing lumen 56 has a generally circular cross sectional surface area and is configured to permit insertion of a thermometry sensor within shaft 32 to monitor the temperature of surrounding prostatic tissue when shaft 32 is inserted within urethra 10. Temperature sensing lumen 56 preferably has a diameter of about 0.032 inches.

First modified portion 72 of catheter wall 68 defines a common wall between antenna lumen 58 and temperature sensing lumen 56. First modified wall portion 72 preferably has a thickness (e.g., 0.020 inches) about two times the otherwise substantially uniform thickness of catheter wall 68. Second modified portion 74 of catheter wall 68 defines an outer wall of temperature sensing lumen 56 and preferably has a thickness (e.g., 0.005 inches) about one-half the otherwise substantially uniform wall thickness of catheter wall 68.

Microwave antenna lumen 58 is positioned eccentric to the longitudinal axis of catheter shaft 32, antenna lumen 58 being positioned nearer

-10-

first side 70 of shaft 32 than second side 76 of shaft 32. Microwave antenna lumen 58 preferably has a generally circular cross-sectional surface area which is larger than a cross-sectional surface area of any of the other respective lumens of catheter shaft 32. Antenna lumen 58 preferably has a diameter of about 0.106 inches. At its distal end, antenna lumen 58 communicates with microwave antenna port 44 of manifold 30. Antenna lumen 58 is adapted for receiving a microwave antenna to be permanently positioned within antenna lumen 58 of shaft 32 near balloon 36 (Fig. 2) so the antenna will be generally situated adjacent benign tumorous tissue of prostate 14 when shaft 32 is properly positioned within urethra 10. A microwave antenna suitable for incorporation into catheter 28 of the present invention is disclosed in Rudie et al. U.S. Patent No. 5,413,588, issued May 9, 1995, and is hereby incorporated by reference.

Urine drainage lumen 60 is positioned adjacent antenna lumen 58 between antenna lumen 58 and second side 76 of shaft 32. Urine drainage lumen 60 has a generally circular cross-sectional surface area defined by catheter wall 68 and preferably has a diameter of about 0.04 inches. Urine drainage lumen 60 communicates with urine drainage port 42 of manifold 30 at distal shaft end 50 and with tip 34 at proximal shaft end 54 to define a drainage path for urine when tip 34 of catheter 28 is inserted within bladder 12. Urine flows into tip 34 through side port 39 (Fig. 2). Drainage of urine from bladder 12 is necessary due to frequent bladder spasms which occur during transurethral thermal therapy.

Balloon inflation lumen 62 is positioned near second side 76 of shaft 32, generally between urine drainage lumen 60 and second side 76. Balloon inflation lumen 62 preferably has a generally circular cross-sectional surface area defined by catheter wall 68 and preferably has a diameter of about 0.04 inches. Balloon inflation lumen 62 communicates with inflation port 40 of manifold 30 for moving balloon inflation fluid in and out of the balloon

-11-

inflation lumen 62. Balloon inflation lumen 62 is provided for supplying an inflation fluid to balloon portion 36 of tip 34.

Cooling fluid intake lumens 64A and 64B are positioned circumjacent antenna lumen 58 and first side 70, being located between first side
5 70 and antenna lumen 58. Cooling fluid intake lumens 64A and 64B are defined by single unitary catheter wall 68 and preferably have a generally arc shaped cross-sectional surface area configured to partially surround antenna lumen 58. Cooling lumens 64A and 64B also preferably have a uniform radial thickness. Cooling fluid intake lumens 64A and 64B extend from distal shaft end 50 to
10 proximal shaft end 54. Fluid contained within intake lumens 64A and 64B absorbs a portion of microwave energy emitted by a microwave antenna within antenna lumen 58 to control the volume of prostatic tissue adjacent first side 70 of shaft 32 that is heated above 45°C. Water within intake lumens 64A and 64B also absorbs heat energy generated by microwave energy from adjacent
15 tissues via thermal conduction. Cooling fluid intake lumens 64A, 64B have a radial thickness of about 0.028 inches and have an inner radius of 0.062 inches and an outer radius of 0.09 inches (relative to a focus of the elliptical cross-section of shaft 32 nearest first side 70).

Cooling fluid exhaust lumens 66A and 66B are generally
20 positioned between second side 76 and antenna lumen 58 and have a generally arc-shaped cross-sectional surface area. First portions 67A and 67B of cooling exhaust lumens 66A and 66B are circumjacent antenna lumen 58 and second portions 69A and 69B are circumjacent second side 76 of catheter shaft 32. The generally arc shaped cross-sectional surface area of cooling fluid exhaust lumens
25 66A and 66B is modified to accommodate the presence of urine drainage lumen 60 between cooling exhaust lumens 66A and 66B. Cooling exhaust lumens 66A and 66B extend from shaft distal end 50 to shaft proximal end 54. Cooling exhaust lumens 66A and 66B are wider in cross section than cooling intake lumens 64A and 64B and have a cross-sectional surface area greater than the

-12-

cross-sectional surface area of cooling intake lumens 64A and 64B. Cooling fluid exhaust lumens 66A, 66B have an outer radius of 0.09 inches (relative to a focus of the elliptical shaft cross section of shaft 32 nearest first side 70). Portion 67A, 67B of lumens 66A, 66B have an inner radius of 0.062 inches
5 (relative to the focus of the elliptical shaft cross section nearest first side 70).

This greater cross-sectional surface area of exhaust lumens 66A and 66B enable water within exhaust lumen 66A and 66B to be capable of absorbing a greater amount of microwave energy when a microwave antenna disposed within antenna lumen 58 is energized. Given the power output
10 currently used with a microwave antenna such as that disclosed in Rudie et al. U.S. Patent No. 5,413,588, the temperature of tissue adjacent second side 76 of shaft 32 will remain below about 45°C. This prevents the portion of urethra 10 adjacent second side 76 from being overheated and damaged when a microwave antenna within antenna lumen 58 is energized.

15 Cooling intake lumens 64A and 64B and exhaust lumens 66A and 66B cooperate with a cooling system via ports 46 and 48 of manifold 30 to provide a selectively controlled flow of fluid through cooling lumens 64A, 64B, 66A, and 66B during a treatment session. This arrangement achieves a desired cooling pattern surrounding a microwave antenna energized within antenna
20 lumen 58 while catheter shaft 32 is within a urethra 10. Cooling intake lumens 64A, 64B and cooling exhaust lumens 66A, 66B can be used with a cooling system under the treatment parameters as described in Rudie et al. U.S. Patent No. 5,413,588, (earlier incorporated by reference) and under the treatment parameters disclosed in pending application U.S. Serial No. 08/309,137, filed
25 September 20, 1994.

Cooling fluid intake lumens 64A and 64B are in communication with cooling exhaust lumens 66A and 66B, respectively, near proximal shaft end 54 of catheter shaft 32 adjacent balloon portion 36 (Fig. 2). As shown in Fig. 4, a portion of catheter wall 68 defining a common wall between cooling intake

-13-

lumen 64A and cooling exhaust lumen 66A has been removed creating hole 77A to permit communication between the respective lumens. Similarly, a portion of catheter wall 68 defining a common wall between cooling intake lumen 64B and cooling exhaust lumen 66B has been removed creating hole 77B to allow
5 communication between the respective lumens 64B and 66B. This configuration permits cooling fluid that is flowing proximally through cooling intake lumens 64A and 64B to enter cooling exhaust lumens 66A and 66B, respectively, to establish a cooling fluid flow loop that cooperates with a cooling system connected to manifold 30.

10 Fig. 5 illustrates a cross section of catheter shaft 32 adjacent a shaft end 54 just proximal to balloon 36 (see Fig. 2). At this location, temperature sensing lumen 56, antenna lumen 58, inflation lumen 62, cooling intake lumens 64A and 64B, and cooling exhaust lumens 66A and 66B are closed by silicone plug material 78 sealing each of these lumens at proximal
15 shaft end 54. However, urine drainage lumen 60 remains open at proximal shaft end 54 so that urine from the bladder may pass through tip 34 and into urine drainage lumen 60.

As shown in Fig. 6, tip 34 comprises a single unitary member including balloon portion 36 and tip portion 38. Balloon portion 36 is a flexible
20 tubular portion having distal end 80, proximal end 82, side wall 84, inner surface 86, ribs 88, and hole 90. Side wall 84 of tubular balloon portion 36 extends between distal end 80 and proximal end 82 and has inner surface 86 with ribs 88 formed thereon extending circumferentially on the inner surface 86. Ribs 88 are visible in Fig. 6 since flexible tubular portion of balloon portion 36
25 is preferably made from a translucent material. Side wall 84 of tubular balloon portion 36 includes hole 90 formed adjacent proximal end 82.

Tip portion 38 comprises a flexible curved body having distal end 92, proximal tip end 94, tip lumen 96, dividing wall 98, and hole 100. Tip lumen 96 extends through a portion of the tip body and communicates with side

-14-

port 39. Side port 39 permits insertion of a guide wire (not shown) into tip lumen 96 to facilitate insertion of intraurethral catheter 28 within urethra 10 in a manner well known in the art. Dividing wall 98 at distal end 92 defines a border between balloon portion 36 and tip portion 38. Wall 98 also defines a distal end of tip lumen 96 and has hole 100 formed therein to permit communication between tip lumen 96 and an interior of tubular balloon portion 36.

Tip 34 is formed by liquid injection molding from a flexible, medical-grade silicone sold by Dow Corning under the trademark Silastic[®] Q-7-4850. The silicone preferably has a material hardness of 20 Shore A, which is relatively soft to provide an atraumatic tip. Tip 34 can also include a radiopaque filler such as barium sulfate added to the silicone material to make tip 34 observable under fluoroscopy.

Tip 34 preferably has a length of 1.95 inches including tip portion 38 which preferably has a length of 0.84 inches. Tubular portion 36 preferably has a length of 1.11 inches including the ribbed portion which has a length of 0.64 inches. Side wall 94 preferably has a thickness of 0.01 inches while ribs 88 preferably have a radius of 0.01 inches and are spaced longitudinally with respect to each other by 0.16 inches. Tubular portion 36 has an elliptical cross section and has a radius of about 0.110 inches, wherein the foci of the ellipse are separated by 0.053 inches. Side wall 94 of tubular portion is capable of elongating up to 400% so that an elliptical cross section of balloon portion 36 when expanded has a cross sectional area about 4 times its cross sectional area in a nonexpanded state.

Fig. 7 provides a more detailed view of catheter shaft 32 and tip 34 at proximal shaft end 54. Proximal shaft end 54 of catheter 28 fits snugly within tubular portion 36 of tip 34 with utmost proximal shaft end 54 resting against dividing wall 98 of tip 34 and outer surface 52 of catheter shaft 32 in

-15-

contact with multiple structures defining an interior of tubular balloon portion 36.

As shown in FIG. 7, urine drainage lumen 60 further includes expanded diameter portion 102 while inflation lumen 62 further includes hole 104. Temperature sensing lumen 56, antenna lumen 58, and inflation lumen 62 further include silicone plug material 78 filled within their proximal ends. Balloon portion 36 of tip 34 further includes first collar 106, second collar 108, first well 110, second well 112, third well 114, adhesive dam 116, first rib 118, and second rib 119.

Expanded diameter section 102 of urine drainage lumen 60 has a generally conical shape and communicates with tip lumen 96 via hole 100 in wall 98 to permit urine flow therethrough. Hole 104 of inflation lumen 62 permits communication between inflation lumen 62 and an interior of balloon portion 36 for inflating and deflating balloon portion 36.

Expanded diameter portion 102 of urine drainage lumen 60 is formed at the time silicone plug material 78 is introduced into the other lumens 32 at proximal shaft end 54. In particular, a syringe tip is introduced into urine drainage lumen 60 at proximal shaft end 54 and maintained in that position while silicone plug material 78 is introduced into all of the remaining lumens defining catheter shaft 32. The introduction of silicone plug material 78 includes the application of heat to proximal shaft end 54, thereby causing urinary drainage lumen 60 to permanently expand and reform about the shape of the syringe tip. Upon setting of the silicone plug material 78, the syringe tip is removed from proximal shaft end 54 resulting in urine drainage lumen 60 having expanded diameter portion 102 and each of the other respective lumens of catheter shaft 32 having sealed ends filled with silicone plug material 78.

First collar 106 of balloon portion 36 defines distal end 80 while second collar 108 defines proximal end 82 with side wall 84 extending therebetween. First well 110 defines a reservoir formed between first collar

-16-

106, first rib 118, and side wall 84 while second well 112 defines a reservoir formed between second collar 108, side wall 84, and adhesive dam 116. Third well 114 defines a reservoir formed between adhesive dam 116, side wall 84, and second rib 119.

5 To secure tip 34 onto proximal shaft end 54, tubular portion 36 is slip fit over proximal shaft end 54 into the position shown in FIG. 7. Next, tubular portion 36 is secured about proximal shaft end 54 with an adhesive. Adhesive is introduced between first collar 106 and shaft outer surface 52 of shaft 32 to create a sealed connection therebetween. First well 110 catches any
10 excess adhesive that wicks proximally beyond first collar 106.

 Side hole 90 is used to introduce adhesive between second collar 108 and shaft outer surface 32 at utmost shaft proximal end 54. Second well 112 receives adhesive introduced through side hole 90 while adhesive dam 116 blocks adhesive from migrating distally toward inner surface 86 of side wall 84.
15 Third well 118 acts as an additional reservoir for catching excess adhesive migrating past adhesive dam 116.

 With first collar 106 and second collar 108 of tubular portion 36 sealingly connected about shaft outer surface 52, side wall 84 remains free to expand relative to shaft outer surface 52 upon introduction of inflation fluid
20 within an interior of balloon portion 36 (via inflation lumen 62 through hole 104). Ribs 88 remain spaced slightly from outer surface 52 and maintain spacing between inner surface 86 of side wall 84 and outer surface 52 of catheter shaft 32. This prevents the silicone material forming balloon portion 36 from sticking to the silicone material forming shaft outer surface 52. In the
25 absence of ribs 88, inner surface 86 of side wall 84 would tend to stick to shaft outer surface 52 and thereby inhibit inflation and expansion of side wall 84.

 Tubular portion 36 is positioned on proximal shaft end 54 so that side wall 84 can be expanded within bladder 12 to maintain a proximal end of a microwave antenna (within catheter shaft 32) spaced at least 4 millimeters

-17-

proximally from the opening of the bladder 12. This positions the microwave antenna within urethra 10 so that healthy prostatic tissue between a tip of the microwave antenna and bladder 12 is preserved.

As shown in Fig. 8, an alternative embodiment of catheter shaft 32 further includes elongate insert 120. Elongate insert 120 includes first end 122 and second end 124. Elongate insert 120 is positioned within temperature sensing lumen 56 alongside sensor 126 of thermal sensing device 128 adjacent microwave antenna 130 positioned within antenna lumen 58. Elongate insert 120 displaces sensor 126 of thermal sensing device 128 radially away from antenna 130 and toward first side 70 of catheter shaft 32.

Fig. 9 illustrates a cross-sectional view of elongate insert 120. Elongate insert 120 has a generally crescent shaped cross-sectional surface area including a concave surface and has a width approximately one-half the diameter of temperature sensing lumen 56. Concave surface 127 of elongate insert 120 is positioned circumjacent sensor 126 between thermal sensing device 128 and antenna lumen 58 to move sensor 126 within temperature sensing lumen 56 as far away as possible from microwave antenna 130 and cooling lumens 64A and 64B. This arrangement increases the accuracy of temperature measurements of surrounding prostatic tissue adjacent shaft first side 70 by better insulating sensor 126 from both heating (microwave antenna) and cooling (cooling fluid) sources within catheter shaft 32. Elongate insert 120, in filling up a portion of the cross sectional area within temperature sensing lumen 56, effectively eliminates excess spacing within lumen 56 that is necessary to permit insertion of thermal sensing device 128 within lumen 56.

Elongate insert 120 can be inserted into temperature sensing lumen 56 either before or after thermal sensing device 128 is positioned within temperature sensing lumen 56. Elongate insert 120 is introduced into temperature sensing lumen 56 by making a cut in first side 70 of catheter shaft 32 adjacent temperature sensing lumen 56 and advancing elongate insert 120

-18-

distally through temperature sensing lumen 56 until elongate insert 120 is completely within temperature sensing 56 and resting on an inner wall of temperature sensing lumen 56. Elongate insert 120 is then held in place against the inner wall of temperature sensing lumen 56 until sensor 126 is properly
5 positioned relative to elongate insert 120. Thereafter, the slit made in first side 70 of catheter shaft 32 is sealed using an adhesive filler. Elongate insert 120 has a length of about one to two inches, a thickness at its center of about 0.013 inches, and a width between its outer edges of about 0.32 inches. Elongate insert 120 is preferably formed from a Teflon[®] material to facilitate sliding
10 movement of sensor 126 relative to insert 120.

As shown in Fig. 10, tubular elongate insert 140 provides an alternative embodiment to crescent shaped elongate insert 120. Tubular elongate insert 140 includes inner surface 142, outer surface 144 and wall 146 defined therebetween. Tubular insert 140 is positioned within temperature sensing
15 lumen 58 and surrounds sensor 126 of thermal sensing device 128. Like elongate insert 120, tubular insert 140 displaces sensor 126 away from antenna 130 and cooling lumens 64A and 64B toward first side 70 of catheter shaft 32, thereby eliminating excess space within temperature sensing lumen 58 and increasing the accuracy of temperature measurements of the surrounding
20 prostatic tissue.

Tubular insert 140 is placed within temperature sensing lumen 58 according to the insertion method described for elongate insert 120. Tubular insert 140 is preferably formed from a Teflon[®] material to facilitate sliding movement of sensor 126 relative to tubular insert 140. Tubular insert 140 has
25 a length of about one to two inches, wall 146 has a uniform radial thickness of about 0.007 inches, and outer surface 144 has a diameter of about 0.032 inches.

In use, catheter 28 of the present invention including multi-lumen catheter shaft 32 and tip 34 including balloon portion 36 is employed according to the insertion method and treatment method described in Rudie et al. U.S.

-19-

Patent No. 5,413,588. Additional urethral treatment parameters can be employed with catheter 28 of the present invention such as that described in U.S. Patent Application Serial No. 08/309,137 filed September 20, 1994 and hereby incorporated by reference.

5 Fig. 11 shows an enlarged view of the male pelvic region of Fig. 1 with catheter 28 properly positioned within urethra 10. Shaft 32 is positioned within urethra 10 with second side 76 of shaft 32 oriented toward rectum 26. Cooling fluid exhaust lumens 66A, 66B are oriented posteriorly, toward rectum 26 and cooling fluid intake lumens 64A, 64B are oriented anteriorly toward
10 fibromuscular tissue 140 of prostate 14. The portion of transition zone 142 anterior and lateral to urethra 10 is the most frequent location of the tumorous tissue growth which causes BPH. Since cooling fluid exhaust lumens 66A, 66B are capable of absorbing more microwave energy than cooling fluid intake lumens 64A, 64B, the radiation patterns created by microwave energy emitted
15 from antenna 144 are asymmetrical. Thus, a relatively large volume of tissue enveloping the anterior portion of transition zone 142, adjacent first side 70, is heated to a temperature above about 45°C, which effectively necroses the tumorous tissue of prostate 14 which encroaches upon urethra 10. In comparison, the temperature of tissue adjacent second side 76 remains below
20 about 45°C, thereby eliminating the harmful effects of the microwave energy to ejaculatory duct 24 and rectum 26.

Catheter 28 of the present invention including multi lumen shaft 32 and tip 34 yield numerous advantages over the prior art. First, multi lumen catheter shaft 32 is configured to maximize exposure of its cooling lumens to
25 an antenna lumen carrying a microwave antenna. This optimized configuration is established by having cooling fluid intake and exhaust lumens with a generally arc shaped cross-sectional area which substantially surround an antenna lumen having a generally circular cross-sectional area. These lumens are defined by a unitary wall having a substantially uniform wall thickness arranged to

-20-

maximize the cross-sectional surface area of the cooling lumens relative to the antenna lumen. Second, a urine drainage lumen of the present invention has a generally circular cross-sectional surface area which tends to remain open even when an intraurethral catheter of the present invention is disposed within a portion of a urethra which bends the intraurethral catheter. In addition, the generally circular cross-sectional area of the urine drainage lumen disposed adjacent the antenna lumen minimizes the relative surface area and exposure between the urine drainage lumen and the antenna lumen. This reduces the effect that variable urine flow within the urine drainage lumen has on microwave antenna tuning and on the consistency of the shape and energy of a microwave radiation pattern generated by the microwave antenna within the antenna lumen.

Finally, the lumens of multi lumen catheter shaft 32 are arranged and shaped to increase the structural integrity of catheter shaft 32 while maximizing the surface area of each of the respective lumens. This is accomplished by defining the respective lumens by a single unitary wall having a substantially uniform wall thickness and by selecting optimal shapes of the cross-sectional surface area of the lumens.

The tip 34 of catheter 28 of the present invention also has numerous advantages. First, a tip comprising a single unitary member including an insertion tip and an inflatable balloon portion greatly simplifies assembly of the catheter. The tip can simply be slip fit over a proximal end of the catheter shaft and secured thereto with an adhesive. The insertion tip portion facilitates insertion and guidance of the catheter of the present invention within the urethra. A balloon of a tip of the present invention is constructed to maintain a low profile in its deflated state to facilitate insertion and passage of the catheter within a urethra. Unlike prior art balloon designs, a balloon of a tip of the present invention does not have any excess material or winged portions which must be folded down or compressed during insertion of or passage of the

-21-

balloon through the urethra. Rather, the unique structure of a balloon of the tip of the present invention yields a balloon which remains relatively flat in its deflated state during passage through the urethra. A tubular portion comprising a balloon of the present invention is arranged and configured to facilitate
5 introducing adhesive for sealing the balloon about an outer surface of the catheter shaft without compromising an effective length of the inflatable portion of the balloon caused by wicking of the adhesive toward an anterior portion of the balloon.

Although the present invention has been described with reference
10 to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

-22-

WHAT IS CLAIMED IS:

1. An intraurethral catheter comprising:
an elongate shaft having a first end, a second end, a first outer
surface, and a second outer surface, the shaft further
5 comprising:
a plurality of lumens which extend between the first end
and the second end of the shaft including,
an antenna lumen having a generally circular
cross-sectional surface area and being
10 positioned nearer the first outer surface
than the second outer surface;
a first pair and a second pair of cooling lumens
substantially surrounding the antenna
lumen wherein the cooling lumens have a
15 generally arc shaped cross-sectional surface
area are configured to be adjacent to the
antenna lumen about a substantial majority
of the antenna lumen; and
a urinary drainage lumen positioned between the
20 second pair of cooling lumens adjacent the
antenna lumen, the urinary drainage lumen
having a generally circular cross-sectional
surface area.
2. The catheter of claim 1 and further comprising:
25 a temperature sensing lumen positioned between the first outer
surface and the antenna lumen and having a generally
circular cross-sectional surface area; and

-23-

an inflation lumen positioned between the second outer surface and the urinary drainage lumen and having a generally circular cross-sectional surface area.

3. The catheter of claim 2, and further comprising a thermal sensing device, the thermal sensing device being positioned within the temperature sensing lumen of the shaft.

4. The catheter of claim 3 and further comprising:
an elongate insert positioned within the temperature sensing lumen alongside the thermal sensing device between the thermal sensing device and the antenna lumen.

5. The catheter of claim 4 wherein the insert has a generally arcuate cross-sectional surface area and a concave surface of the insert is adjacent to the thermal sensing device.

6. The catheter of claim 3 and further comprising:
a tubular elongate insert positioned within the temperature sensing lumen and surrounding the thermal sensing device.

7. The catheter of claim 2 wherein the lumens of the catheter are defined by a single unitary wall having a substantially uniform thickness throughout the catheter.

8. The catheter of claim 1, and further comprising a heating device, the heating device being positionable within the antenna lumen of the shaft.

9. The catheter of claim 1 wherein a portion of the second pair of cooling lumens has a radial thickness about two times the radial thickness of the first pair of cooling lumens.

10. An intraurethral catheter comprising:
an elongate shaft having a first end, a second end, a first outer surface, a second outer surface, and a plurality of lumens which extend between the first end and the second end of

-24-

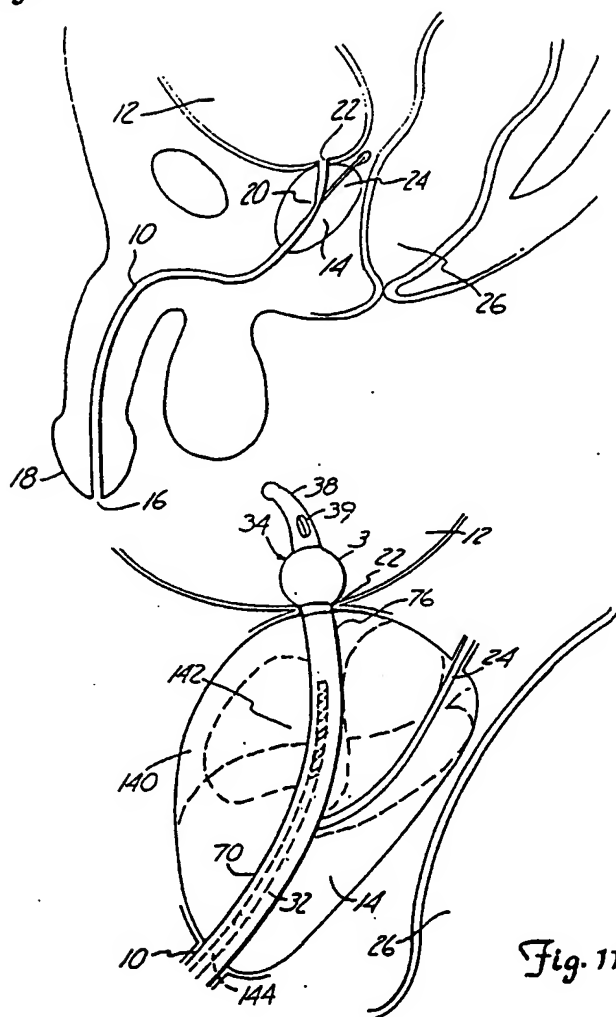
the shaft, the lumens being defined by a unitary wall having a substantially uniform wall thickness, and the shaft further comprising:

5 an antenna lumen having a generally circular cross-sectional surface area, wherein the antenna lumen is oriented nearer the first outer surface than the second outer surface; and

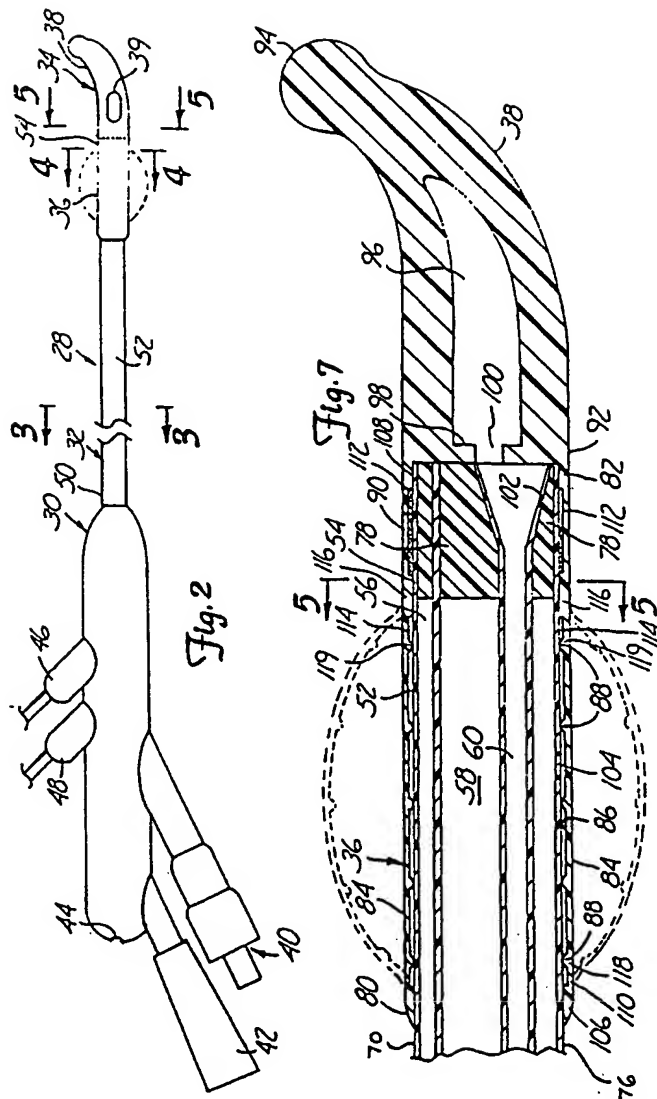
10 a first and second pair of cooling lumens and a urinary drainage lumen arranged to substantially surround the antenna lumen wherein an inner wall of the cooling lumens and the urinary drainage lumen are common with a wall defining the antenna lumen so that each of the cooling lumens and the urinary drainage lumen are spaced from the antenna lumen
15 by no more than the substantially uniform wall thickness.

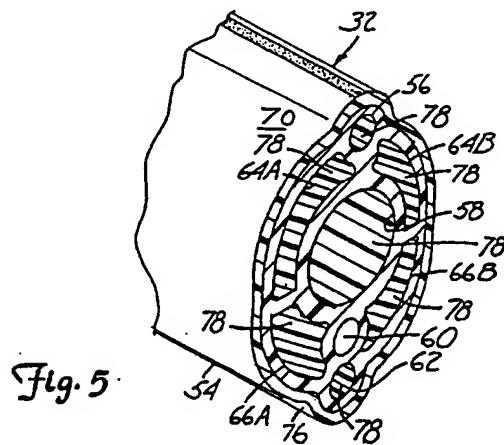
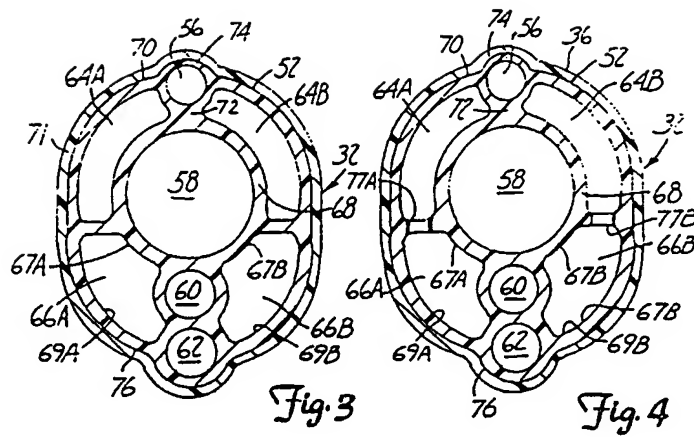
SHEET 1 OF 4

Fig. 1

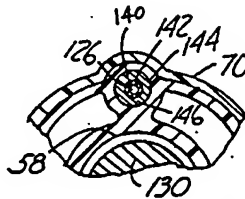
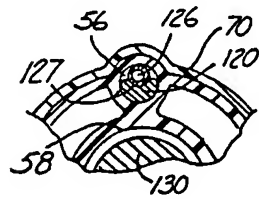
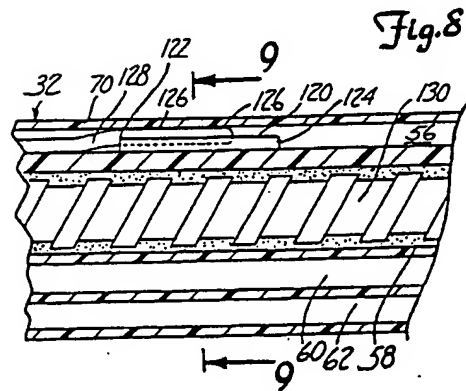
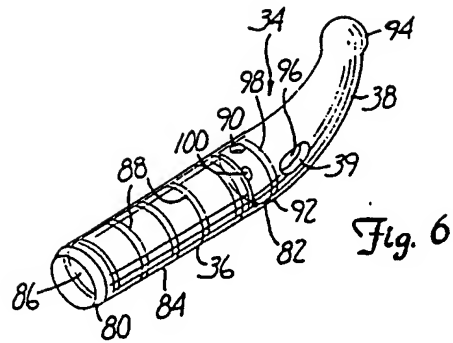


SHEET 2 OF 4





SHEET 4 OF 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/07878

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/02

US CL :607/101, 102, 105, 113, 156

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96-98; 607/101-105, 113, 156

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,413,588 (RUDIE ET AL.) 09 May 1995. see entire document.	1-10
Y, P	US, A, 5,464,437 (REID ET AL.) 07 November 1995, see entire document.	1-10
Y	US, A, 5,234,004 (HASCOET ET AL.) 10 August 1993, see entire document.	4-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 01 JULY 1996	Date of mailing of the international search report 08 AUG 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No.: (703) 305-3590	Authorized officer <i>Herman J. Robinson</i> HERMAN J. ROBINSON Telephone No. (703) 308-2909

**PThis Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☒ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.